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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,405	11/30/2004	Wolfgang Demmer	DES: 3568.0099	2828

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EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/516,405

Applicant(s)

DEMMER ET AL.

Examiner

Susan E. Fernandez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-15 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/21/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The response filed August 18, 2006, has been received and entered.

Claims 1-15 are pending. Claims 1-10 are withdrawn.

#### ***Election/Restrictions***

As discussed in the previous office action, applicant's election of Group II, claims 11-15, in the reply filed on May 5, 2006, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant's election with traverse of the species from claim 13 ((a) bestatin, (b) leupeptin, (c) p-aminobenzamidine) in the reply filed on August 18, 2006, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11-15 are examined on the merits to the extent they read on the elected subject matter and species.

***Claim Objections***

Claim 13 is objected to because of the following informalities: Line 4 of the claim recites "cystein," which is the misspelling of the term "cysteine." Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burtin et al. (US 6,248,238).

Burtin et al. discloses a medical apparatus for the extracorporeal treatment of blood or plasma, comprising a semi-permeable membrane (column 4, lines 34-36). This semi-permeable membrane has an anti-protease agent bound to it by an ionic interaction with the electronegative

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sites of the membrane (column 4, lines 40-45), thus the anti-protease agent (protease inhibitor) is coupled to the membrane via functional groups. Furthermore, the apparatus clearly comprises a housing having a fluid inlet and a fluid outlet (see Figure 5).

Burtin et al. differs from the claimed invention in that it does not expressly disclose a device comprising four of the membranes with protease inhibitor coupled to the membrane via functional groups.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used multiple membranes in series in the Burtin apparatus. One of ordinary skill in the art would have been motivated to do this in order to have ensured thorough extracorporeal treatment of blood or plasma.

Note further that according to MPEP 2114, "a claim containing a 'recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches all the structural limitations of the claim." Given that all the structural limitations described in instant claim 11 are rendered obvious by Burtin et al., the invention renders obvious the intended use of removing proteases from biological fluids and pharmaceutical solutions.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nussbaumer et al. (US 6,294,090) in view of Nemori et al. (WO 01/71025, English language equivalent US 7,067,272) and Bergmann (US 5,168,041).

Nussbaumer et al. discloses an adsorptive separation device for separations by permeation of liquids comprising a housing, a liquid input, a liquid output, and a porous

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adsorption membrane (abstract and claim 1). Additionally, the device may comprise multiple adsorption membranes with different adsorption properties (claims 14 and 15). Thus, a device comprising even up to four adsorption membranes is rendered obvious. Note that the device may be used for the selective separation and purification of enzymes from media (column 3, lines 20-23).

Nussbaumer et al. differs from the claimed invention in that it does not teach that the adsorption membranes comprise functional groups which are chemically coupled with protease inhibitors which selectively bind with proteases.

Nemori et al. discloses thin membranes comprising a protease inhibitor, where the inhibitor is for matrix metalloproteinase or serine protease or cysteine protease, preferably (column 2, lines 45-51 of English equivalent). A list of protease inhibitors for inclusion in the membranes is listed in column 9, lines 23-37 of the English equivalent, but it is noted that "...the protease inhibitor are not limited to these compounds" (column 9, lines 37-39 of English equivalent).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used the thin membranes comprising protease inhibitor described in Nemori et al. in the separation device described in Nussbaumer et al. in order to remove proteases from fluids. One of ordinary skill in the art would have been motivated to do this the Nemori membranes would have successfully served as porous adsorption membranes, as required by the Nussbaumer invention, and would have allowed for the selective separation and purification of enzymes from media, which is taught as a use of the Nussbaumer invention. Note that though Nemori et al. does not expressly teach that the protease inhibitors are chemically

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coupled to functional groups in the membranes of Nemori et al., it would have been obvious that such is occurring in order for the protease inhibitors to be bound to the Nemori thin membranes. In combining the Nussbaumer invention with the Nemori invention, a device including up to four Nemori thin membranes is rendered obvious, given the teaching of claims 14 and 15 of Nussbaumer et al. Thus, claims 11 and 15 are rendered obvious.

The references differ from the claimed invention in that they do not teach using different protease inhibitors in each of the adsorption membranes of the device rendered obvious by Nussbaumer et al. and Nemori et al., or that each membranes contains two different protease inhibitors, or that the protease inhibitors are any of the compounds (pepstatin and the elected species) recited in instant claim 13.

Bergmann lists various protease inhibitors on Table 1 at column 4, where the table includes pepstatin and the elected species recited in instant claim 13.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used different compounds as the protease inhibitors present in the membranes of the device, where the different compounds may be present in different membranes and/or combined with other protease inhibitors in the same membrane. One of ordinary skill in the art would have been motivated to do this in order to have separated a variety of proteases from a solution, or to have ensured that a specific protease is indeed separated from a solution. It would have been obvious to have used compounds recognized in the art as protease inhibitors, such as those listed in Table 1 at column 4 of Bergmann, in the device, as Nemori et al. does not limit the protease inhibitor included in its thin membranes (column 9, lines 37-39 of English equivalent). Thus, claims 12-14 are also rendered obvious.

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A holding of obviousness is clearly required.

No claims are allowed.

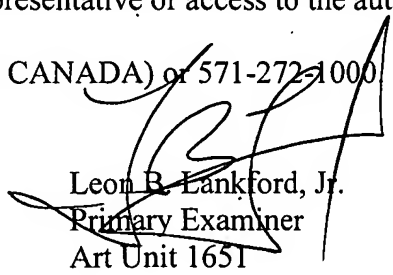
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444.

The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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